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Meril's Myval Transcatheter Heart Valve receives CE approval

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Meril Life Sciences becomes the first and currently only Indian company to market and distribute its patented Transcatheter Heart Valve (THV): MyvalTM -THV System to Europe & other Countries

Recently, *Myval*^{TM} received the coveted CE approval. Meril now becomes the first Indian company to market and distribute its indigenously designed and patented TAVR technology, *Myval*^{TM} -THV system, to European Union and other countries.

The CE certification is a conformity mark indicating the product to be compliant with the European Union (EU) health standards. The CE certification would enable *Myval*^{TM} -THV to reach over 60 countries in Europe and outside of India which accept CE mark document for their own regulatory approvals.

TAVR is an established treatment modality for patients who are at a risk or unwilling to undergo open heart valve replacement surgery. TAVR is a minimally invasive procedure that repairs the aortic heart valve without removing the old, damaged valve. Instead, it places a replacement valve through a catheter or tube inserted through the femoral artery (the large artery in the groin). The TAVR procedure is also beneficial for treating patients with previous failed bioprosthetic valve, hence preventing an additional surgical intervention.

The *Myval*^{TM} THV System has a Hybrid honey comb design, on crimping it has a distinct alternating dark-light banding pattern visible under fluoroscopy. This unique pattern helps in precise placement of the valve and ensures orthotopic deployment. *Myval*^{TM} THV gets crimped on a Navigator delivery system which comes with a dual-stopper system ensuring valve crimping is precise and snug. The *Myval*^{TM} System includes Mammoth balloon dilatation catheter, 9F low profile, for valvuloplasty. The kit also includes atraumatic and lubricious coated Python introducer sheath, 14F low Profile which allows for percutaneous access of the crimped *Myval*^{TM} THV.

Meril Life Sciences got CE and Central Drugs Standard Control Organization (CDSCO) approval for *Myval*^{TM} technology basis the results of MyVal-1 Study. One-year clinical outcomes from the MyVal-1 study demonstrated 100% acute procedural success and no device-related mortality as reported at EuroPCR 2019 (21-24 May).

The data were presented in a Late-breaking trial session at EuroPCR'2019 Conference at Paris by the trial's Principal investigator, Dr Ashok Seth, Chairman of Fortis Escorts Heart Institute, New Delhi, India. Dr Seth explained that in addition to the procedural success and zero device-related mortality rate, there were also no new pacemaker implantations, no strokes and no paravalvular leaks observed in the trial patients. Furthermore, Echo parameters were maintained at 12-month follow-up and there was a significant improvement in Quality of Life of the patients as demonstrated by tests including NYHA functional class.

Sanjeev Bhatt, Vice President Corporate Strategy, Meril Life Sciences said, "We are excited by these results. Since its inception, Meril has played a leading role in developing and introducing innovative medical technologies. Our *Myval*^{TM} Transcatheter Heart Valve technology is an assertion of this fundamental belief and after being granted the CE mark, we get set to launch it across Europe. It's a proud moment not just for us but for India to be able to make this indigenous innovation available globally."

Meril is a global medical device company operating in more than 100 countries with a diverse operational canvas from Vascular Interventional devices to Orthopedics, In-vitro diagnostics and Endo-Surgery.